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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/052,812 01/18/2002 Sergiu Silvian A02P1003 3212 EXAMINER 36802 7590 03/30/2005 PACESETTER, INC. EVANISKO, GEORGE ROBERT 15900 VALLEY VIEW COURT PAPER NUMBER ART UNIT SYLMAR, CA 91392-9221 3762

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

			SH
	Application No.	Applicant(s)	
	10/052,812	SILVIAN ET AL.	
Office Action Summary	Examiner	Art Unit	
	George R Evanisko	3762	
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the	correspondence address	
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be within the statutory minimum of thirty (30) dill apply and will expire SIX (6) MONTHS fro cause the application to become ABANDON	timely filed  ays will be considered timely.  m the mailing date of this communi- NED (35 U.S.C. § 133).	cation.
Status			
1) Responsive to communication(s) filed on 14 Fe	ebruary 2005.		
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.		
3) Since this application is in condition for allowar	nce except for formal matters, p	rosecution as to the meri	its is
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11,	453 O.G. 213.	
Disposition of Claims			
4)⊠ Claim(s) <u>1-22 and 24-30</u> is/are pending in the	application.		
4a) Of the above claim(s) is/are withdraw			
5)⊠ Claim(s) <u>7 and 16</u> is/are allowed.			
6)⊠ Claim(s) <u>1-6,8-15 and 17-30</u> is/are rejected.			
7) Claim(s) is/are objected to.			
8) Claim(s) are subject to restriction and/o	r election requirement.		
Application Papers			
9) The specification is objected to by the Examine	r.		
10) The drawing(s) filed on is/are: a) acc		e Examiner.	
Applicant may not request that any objection to the			
Replacement drawing sheet(s) including the correct	ion is required if the drawing(s) is o	objected to. See 37 CFR 1.1	121(d).
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	ce Action or form PTO-15	52.
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(	(a)-(d) or (f).	
a) All b) Some * c) None of:			
1. Certified copies of the priority document	s have been received.		
2. Certified copies of the priority document	s have been received in Applica	ation No	
3. Copies of the certified copies of the prior	rity documents have been recei	ved in this National Stage	е
application from the International Bureau	(PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list	of the certified copies not recei	ved.	
Attachment(s)			
1) Notice of References Cited (PTO-892)	4) Interview Summa		•
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	Paper No(s)/Mail 5)  Notice of Informa	Patent Application (PTO-152)	
Paper No(s)/Mail Date	6) Other	•	

#### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/14/05 has been entered.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-15, 17-22, and 24-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the specification is the bypass capacitors being "about" 20-50 microfarads. The original specification stated that the capacitors were "on the order" of 20-50 microfarads (page 15, line 9). (It is suggested to change "about" to "on the order of".)

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 11, 28, and 29 are rejected under 35 U.S.C. 103(a) as obvious over Kerver et al (5964787). Kerver uses a charge pump, figure 1E, with bypass capacitor, 29, that is disconnected during no charge cycles (the claimed "quiescent period") to deliver charge to the delivery capacitor, 37, with microprocessor/controller, 45, controlling the clock/switches. Also, Kerver shows the bypass capacitor across the battery in figure 1E and is inherently a high frequency filter since it is coupled across the battery and will filter out stray noise. In addition, Kerver states in column 4, lines 54-57, that the charge pump (bypass capacitors) can use different pump capacitor configurations, resulting in different values of C eff, to control the current value of the pulses. This provides a clear suggestion that Kerver can be modified to

change the capacitance to values on the order of 20-50 microfarads to control the current of the pulses. The determination of the most appropriate capacitance by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the medical art.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the capacitors as taught by Kerver with a capacitance of about 20-50 microfarads, because Applicant has not disclosed that providing a capacitance of 20-50 microfarads provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with charge pump capacitance as taught by Kerver, because it provides a reduced size pacer by using smaller capacitors to provide the current for the stimulation pulses.

Therefore, it would have been an obvious matter of design choice to modify Kerver to obtain the invention as specified in the claim(s).

Claims 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerver et al.

Kerver discloses the claimed invention except for the bypass capacitor being ceramic capacitors and the delivery capacitor being electrolytic capacitors. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation system as taught by Kerver, with the bypass capacitor being ceramic capacitors and the delivery capacitor being electrolytic capacitors since it was known in the art that stimulation systems use the bypass capacitor being ceramic capacitors to provide capacitors that are free of outgassing, don't need reforming, and have a low resistance, and the delivery capacitor being

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electrolytic capacitors to provide low leakage current capacitors and capacitors that take up less area.

Claims 1, 20, 28, and 30 are rejected under 35 U.S.C. 103(a) as obvious over Kroll (5620464). Kroll provides a bypass capacitor, 74, that inherently acts as a high pass filter since the capacitor will inherently filter any high pass signals from the battery and/or transient signals. Also, Kroll uses switch 76 to connect and disconnect the capacitor to primary and switch 83 to turn primary on and off to deliver the charge to delivery capacitor 32 for heart electrodes 40 and 41. In addition, Kroll states he selectively activates switch 76 when fibrillation is detected and therefore the switch is turned off during a non charging, non-fibrillation, quiescent time (column 5 and claims).

Kroll discloses the claimed invention but does not disclose expressly the capacitors being about 20-50 microfarads. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the capacitor charging system as taught by Kroll with the capacitors being about 20-50 microfarads, because Applicant has not disclosed that the capacitors being 20-50 microfarads provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the capacitors being 1.5 farads as taught by Kroll, because it provides a quick, effective way to charge the delivery capacitor.

Therefore, it would have been an obvious matter of design choice to modify Kroll to obtain the invention as specified in the claim(s).

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In the alternative for claims 1 and 20, Kroll discloses the claimed invention except for the controller disconnecting the capacitor from the battery after charging during a quiescent period. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable device as taught by Kroll, with the controller disconnecting the capacitor from the battery after charging during a quiescent period since it was known in the art that implantable devices use a controller to disconnect electrical components, such as capacitors, A/D converters, sensors, etc, from the battery after they have been used for their function, such as after charging, during a quiescent period, to reduce current/power drain from the battery and extend the life of the implant.

Claims 2-6, 10-15, 19, 21, 22, 24, 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al.

Kroll discloses the claimed invention having heart electrodes and first primary switch 83, except for the leads for the electrodes (claims 2, 21, and 22), the high frequency alternating signal to the first switch (claims 3, 4, 6, 12, 13, 15, and 24), the controller determining the state of charge of the delivery capacitor to enter the charging cycle or to stop charging the bypass capacitor (claims 11 and 24), and the bypass capacitor being ceramic capacitors and the delivery capacitor being electrolytic (claims 10 and 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the defibrillator system as taught by Kroll, with leads for the electrodes, the high frequency alternating signal to the first switch, the controller determining the state of charge of the delivery capacitor to enter the charging cycle or to stop charging the bypass capacitor, and the bypass capacitor being ceramic capacitors and the delivery capacitor being electrolytic since it was known in the art that

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defibrillator systems use: leads for the electrodes so the defibrillator can be placed in a different location in the body but still provide the pulses directly to the heart; the high frequency alternating signal to the first switch to allow the primary to deliver charge to the secondary of the transformer and thereby deliver the energy to the delivery capacitor; the controller determining the state of charge of the delivery capacitor to enter the charging cycle or to stop charging the bypass capacitor to only use battery power when the capacitors are in need of charging; and the bypass capacitor being ceramic capacitors to provide capacitors that are free of outgassing, don't need reforming, and have a low resistance, and the delivery capacitor being electrolytic to provide a high energy density per unit volume and low leakage current capacitor.

In addition, Kroll discloses the claimed invention but does not disclose expressly the capacitors being about 20-50 microfarads. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the capacitor charging system as taught by Kroll with the capacitors being about 20-50 microfarads, because Applicant has not disclosed that the capacitors being 20-50 microfarads provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the capacitors being 1.5 farads as taught by Kroll, because it provides a quick, effective way to charge the delivery capacitor.

Therefore, it would have been an obvious matter of design choice to modify Kroll to obtain the invention as specified in the claim(s).

Allowable Subject Matter

Claims 7 and 16 are allowed.

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Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in

view of the new ground(s) of rejection necessitated by amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to George R Evanisko whose telephone number is 571 272 4945.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eorge R Evan

George R Evanisko Primary Examiner Page 8

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7/24/05

GRE

March 24, 2005